

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

TEVA PHARMACEUTICAL INDUSTRIES
LTD. and TEVA PHARMACEUTICALS USA,
INC.,

Plaintiffs,

V.

AMGEN INC.,

Defendant.

Civil Action No. _____

COMPLAINT FOR PATENT INFRINGEMENT

For their Complaint against Defendant Amgen, Inc. (“Amgen” or “Defendant”), Plaintiffs Teva Pharmaceutical Industries Ltd. (“Teva Ltd.”) and Teva Pharmaceuticals USA, Inc. (“Teva USA”; together, “Teva”) allege as to their own acts, and on information and belief as to the acts of others, as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the Patent Laws of the United States, 35 U.S.C. § 1 et seq., and seeking damages and injunctive relief under 35 U.S.C. §§ 271, 281, 283–285.

THE PARTIES

2. Plaintiff Teva Ltd. is a corporation organized under the laws of Israel and maintains its principal place of business at 5 Basel Street, Petah Tiqva 49131, Israel.

3. Plaintiff Teva USA is a Delaware corporation with its principal place of business located at 1090 Horsham Road, North Wales, Pennsylvania, 19454-1090. Teva USA is an indirect wholly-owned subsidiary of Teva Ltd.

4. On information and belief, Defendant Amgen is a corporation organized and existing under the laws of the State of Delaware with its principle place of business located at One Amgen Center Drive, Thousand Oaks, California 91320-1799.

JURISDICTION AND VENUE

5. This Court has subject matter jurisdiction over this controversy under 28 U.S.C. §§ 1331 and 1338(a), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

6. This Court has personal jurisdiction over Amgen because Amgen is licensed to do business in the State of Pennsylvania and continuously, systematically, and purposefully conducts business within this District, including but not limited to the business of developing, manufacturing, and selling various pharmaceutical products, many of which are marketed, distributed, and sold in Pennsylvania.

7. Venue is proper in this judicial district based on 28 U.S.C. § 1400(b) and/or 28 U.S.C. § 1391(b) and (c).

FACTUAL BACKGROUND

8. Cinacalcet hydrochloride is a member of a class of drugs known as calcimimetics that are useful in the treatment of secondary hyperparathyroidism and hypercalcemia, diseases that are common for patients with chronic renal failure who are on dialysis. Upon information and belief, Amgen holds the approved New Drug Application (“NDA”) No. 21-688 for cinacalcet hydrochloride, which Amgen commercially markets in the United States under the brand name SENSIPAR[®]. Upon further information and belief, Amgen’s NDA for cinacalcet hydrochloride was approved by the FDA on March 8, 2004.

9. Upon information and belief, Amgen engages in the manufacture, importation, use, sale, and/or offer for sale of cinacalcet hydrochloride tablets in 30 mg, 60 mg, and 90 mg dosages in the United States.

THE PATENT-IN-SUIT

10. Teva Ltd. is the owner of all right, title, and interest in U.S. Patent No. 7,449,603 (“the ‘603 Patent”), entitled “Process for the Preparation of Cinacalcet Base,” which was duly and legally issued by the United States Patent and Trademark Office on November 11, 2008. A copy of the ‘603 Patent is attached hereto as Exhibit A.¹ The ‘603 Patent’s claims relate, *inter alia*, to a process for preparing cinacalcet and certain intermediates thereof.

DEFENDANT’S INFRINGEMENT OF THE PATENT-IN-SUIT

11. Upon information and belief, Amgen infringes one or more claims of the ‘603 Patent by its manufacture, importation, use, sale, and/or offer for sale of cinacalcet hydrochloride tablets which are made in part by use of a process that infringes the ‘603 Patent.

12. As a direct and proximate cause of the infringement by Amgen and unless Amgen is enjoined by the Court from manufacturing, importing, offering to sell, selling, or using within the United States products made using Teva’s patented processes, Teva is being and will continue to be substantially and irreparably harmed in its business and property rights.

13. Additionally, Teva is suffering injury for which it is entitled to monetary relief as a result of Amgen’s infringement.

¹ A Certificate of Correction issued for the ‘603 Patent on March 31, 2009, correcting an apparent clerical error, originally describing an intermediate compound as “N-[(1*S*)-1-(1-naphthyl)ethyl]-3-[3- (trifluoromethyl)phenyl] propanamide” instead of “N-[(1*R*)-1-(1-naphthyl)ethyl]-3-[3- (trifluoromethyl)phenyl] propanamide.” The Certificate of Correction is appended to the end of the ‘603 Patent at Exhibit A.

14. As a result of Amgen's ongoing infringement of the '603 Patent, an immediate and justiciable controversy exists between Amgen and Teva regarding the infringement and validity of the '603 Patent.

COUNT I
(Amgen's Infringement of the '603 Patent)

15. Teva incorporates by reference the allegations contained in Paragraphs 1–14 of the Complaint as if fully set forth herein.

16. On information and belief, the ongoing manufacture, importation, use, sale, and/or offer for sale by Amgen of cinacalcet hydrochloride tablets infringes, either literally or under the doctrine of equivalents, one or more claims of the '603 Patent, or contributes to or induces such infringement, under 35 U.S.C. § 271.

17. On information and belief, Amgen's infringement of the claims of the '603 patent has been and continues to be willful.

PRAYER FOR RELIEF

WHEREFORE, Teva respectfully requests that this Court enter a Judgment and Order:

- (a) Declaring that the '603 Patent is valid and enforceable;
- (b) Declaring that Amgen infringes, either literally or under the doctrine of equivalents, at least one valid and enforceable claim of the '603 Patent, or contributes to or induces such infringement, under 35 U.S.C. § 271;
- (c) Declaring that Amgen's infringement is willful and Teva is entitled to treble damages under 35 U.S.C. § 284;
- (d) Awarding Teva damages adequate to compensate for Amgen's infringement, but in no event less than a reasonable royalty;

(e) Preliminarily and permanently enjoining Amgen, its officers, agents, servants, and employees and those persons in active concert or participation with any of them from manufacturing, importing, offering to sell, selling, or using within the United States products made using Teva's patented processes;

(f) Declaring that this is an exceptional case under 35 U.S.C. § 285 and awarding Teva its attorneys' fees, costs, and expenses, based in part on, but not limited to, Amgen's willful infringement; and

(g) Granting Teva such other and further relief as this Court deems just, proper, and equitable.

Dated: May 20, 2009

Respectfully Submitted,

Stevens & Lee, P.C.

s/ Joseph Wolfson JW383

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